WDN/TMH:dv 12/31/03 CLA/P015700US
PATENT

Attorney Reference Number 5585-59112
Application Number 09/868,605

Remarks

Amendments to the Claims

Claims 1-26 were pending in this application, and subject to a Restriction Requirement. Claims 3-5 were withdrawn by the examiner, for allegedly being so indefinite that they cannot be included in any Group. Applicants have cancelled claims 3 and 4 as being drawn to subject matter corresponding to non-elected Groups, and have amended Claim 5 so that it depends from Claim 2. This provides antecedent basis for the objected to term (peptide), and clearly indicates that Claim 5 belongs Examiner's Groups 2-479,996,686.

Claims 2 and 9 are amended in response to the election made herein. Claim 25 has been amended to correct an obvious clerical error. New Claims 27 and 28 are added; support for the language of these claims can be found at least at page 13, line 26.

Claims 3, 4, 10, 11, 16-23, and 26 are cancelled herein as containing subject matter in non-elected Groups. Applicants expressly reserve the right to pursue protection of any or all of the subject matter of the cancelled claims in a subsequent application.

No new matter is introduced by these amendments. After entry of this amendment, **Claims 1, 2, 5-9, 12-15, 24, 25, 27, and 28 are pending in the application.**

Telephone Conference

Applicants thank Examiner Canella for speaking with their undersigned representative on December 31, 2003. During that telephone conference, the current Restriction Requirement was discussed. The Examiner agreed to reconsider the Requirement. This Response has been prepared in accordance with the Examiner's helpful suggestions.

Provisional Election

Applicants hereby provisionally elect one of Examiner's Groups 2-479,996,686, with traverse. It is believed that each of these Groups is drawn to a method of improving tolerance to a xenograft comprising immunizing a mammal with an immunogen comprising at least one T-

cell epitope and at least one porcine polypeptide B-cell epitope and the T-cell epitope comprises a tetanus toxoid polypeptide, and a composition comprising at least one T-cell epitope and at least one porcine polypeptide B-cell epitope. From within this category of Groups, Applicants elect with traverse that specific Group (of Groups 2-479,996,686) in which the B-cell epitope is derived from CD86, and the specific B-cell epitope is "peptide 6" CSSTQGYPEPQR (corresponding to positions 151 to 162 in SEQ ID NO: 14; illustrated in Figure 26, and more specifically identified in Figure 12). This specific elected Group encompasses claims 1, 2-in-part drawn to at least one B-cell epitope derived from CD86, 5 (as discussed above), 6, 7, 8, 9-in-part drawn to B-cell epitopes, 10, 11-in-part, 12-in-part, 13-15, 24, and 25. This provisional election is made with traverse.

Response to Restriction Requirement

Applicants request that the Examiner reconsider the Restriction Requirement, and either modify it as requested below or withdraw it in its entirety.

It is noted that Unity of Invention was established during the International Stage of this application. Moreover, the alleged different inventions do share a single or corresponding special technical feature or inventive concept over the known art, namely improving tolerance to a xenograft using a method that comprises immunizing a mammal with an immunogen comprising at least one T-cell epitope and at least one porcine polypeptide B-cell epitope, wherein said B-cell epitope is capable of mediating rejection of said xenograft. The Examiner has not identified a reference that anticipates this feature of claim 1 or any of the other claims; similarly, no such reference was identified during the International Stage of this application, as evidenced by the prior finding of Unity. It therefore would be inappropriate to divide the claims into multiple groups under the Unity of Invention standard, because all of the alleged Groups share a special technical feature (the within the meaning of PCT Rule 13.2). Applicants therefore request that the Restriction Requirement be withdrawn.

If the Requirement is not withdrawn, Applicants at least request that it be modified as regards the requirement to select a single B-cell epitope peptide from CD86 (which is illustrated in Figure 26 and Figure 12 (porcine CD86)).

Applicants note also that Figure 26 **does not** define only four possible B-cell epitope peptides, as implied in the Restriction Requirement. The four underlined sequences instead delineate regions of CD86 that are merely preferred (rather than required) for selection of B-cell epitope peptides. The specification makes it clear that these are not the only regions from which peptides can be selected (see, *e.g.*, page 13, lines 20-24).

Nor does the specification require that the sequences underlined in Figure 26 be used in their entirety to form B-cell epitope peptides. This is emphasized in, for instance, Figure 12, which provides specific peptides that are sub-portions of the four underlined regions in Figure 26. The specification also makes it clear that the B-cell epitopes selected can be shorter than the underlined sequences. By way of example, the specification expressly discusses peptides as short as 9 amino acids (see page 12, line 26).

Applicants contend that all B-cell epitope peptides from within the porcine CD86 protein are clearly linked by a single inventive concept, and can be adequately searched in a single database search using SEQ ID NO: 14 (the sequence of porcine CD86). There is no increase in the burden on the Examiner to search for any and all B-cell epitope peptides within the CD86 protein, since only one search is required. Applicants therefore respectfully request that the Requirement for Restriction be modified, at least by not requiring election of a single CD86 peptide.

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Conclusion

Examiner Canella is invited to telephone the undersigned if any questions remain concerning the requirement for restriction, or the amendments made herein. Otherwise, the present application is ready for substantive examination, and such action is requested.

Respectfully submitted,

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